JAN - 4 2012

9. 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: _____

Applicant Information:

Date Prepared:	December 1, 2011
Name:	BridgePoint Medical
Address:	13355 10th Ave N, #110 Plymouth, MN 55441 Phone: 763-225-8500 Fax: 763-225-8718
Contact Person:	Jill Munsinger
Phone Number:	office: 763-225-8510 / cell: 651-270-0572
E-mail:	jmunsinger@bridgepointmedical.com

Device Information:

Classification:	Class II Percutaneous Catheter
Trade Name:	BigBoss™ Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter

Predicate Devices:

The BridgePoint Medical BigBoss™ Catheter is substantially equivalent in intended use, method of operation and technical aspects to the following predicate device:

K081130 and K091841 – CrossBoss™ Catheter

Device Description:

The BigBoss™ Catheter is a single use, over-the-wire, disposable percutaneous catheter consisting of a full length coiled stainless steel shaft with Pebax exterior. The coiled shaft provides torque and makes it possible to push the device, and also provides a guidewire lumen. The device will be available in two models that are differentiated by the distal shaft stiffness. The distal shaft stiffness is specified by the distal grind dimensions of the coiled shaft component. The distal shaft transitions to an enlarged (1mm diameter) rounded distal tip. This stainless steel tip provides an atraumatic element that is intended to enhance the catheter's ability to move within the vasculature with reduced risk of arterial tissue engagement while providing radiopaque visibility. The BigBoss Catheter is hydrophilic coated to enhance lubricity. A torque device, coaxially positioned over the proximal portion of the BigBoss Catheter, provides a

comfortable user interface for device manipulation. The torque device (similar to a guidewire torque device) is positionable along the proximal portion of the catheter and includes a torsion release safety mechanism. This safety mechanism insures the torque input generated by the use remains within the torsional operating strength of the catheter shaft.

Intended Use:
The BridgePoint Medical BigBoss™ Catheter is intended to be used in conjunction with a guidewire in order to access discrete regions of the peripheral vasculature. It may be used to facilitate placement of guidewires and other interventional devices.

Comparison to Predicate Device(s):
The BigBoss™ Catheters are substantially equivalent to the CrossBoss™ Catheter, K081130 and K091841 in that they are both designed to access discrete regions of the peripheral vasculature.

The BigBoss™ Catheters are constructed of similar materials as the CrossBoss Catheter. Modifications were made to the coiled shaft dimensions. The CrossBoss™ Catheters and BigBoss™ Catheters are manufactured using similar processes and components and have similar physical attributes (torque fatigue, trackability, tensile, and radiopacity, etc.).

Performance Data:
The BigBoss™ Catheters have been evaluated using the following *in vitro* bench testing to confirm the performance characteristics as compared to the predicate device:

- Tensile
- Dimensional
- Guidewire Insert & Withdrawal
- Device Shaft Tip Deflection & Trackability
- Kink Resistance
- Coating
- Torque
- Surface Defects
- Corrosion Resistance
- Luer and Hub Tests,
- Radiopacity, and
- Packaging

In vivo testing was also completed in accordance with 21 CFR Part 58, "Good Laboratory Practices for Nonclinical Laboratory Studies." The functional performance and safety of the BigBoss™ Catheters were evaluated in a porcine animal model. BigBoss™ Catheters were inserted into four arteries in each of six animals used for the evaluation. The vessels were evaluated angiographically followed by histology and pathology. Hematology and serum chemistry along with gross necropsy were also used for evaluations. There were no reported complications during each treatment. All six-

animals survived the in-life period with no angiographic evidence of vessel injury or downstream embolism and no abnormal pathologic findings.

Biocompatibility testing was successfully completed and demonstrates the materials and processes used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with the intended use. The following Biocompatibility tests were completed:

- Cytotoxicity L929 MEM - ISO
- Kligman Sensitization (Maximization) - ISO
- Irritation- Intracutaneous Injection - ISO
- Acute Systemic Cytotoxicity - ISO
- Pyrogen – ISO
- Hemocompatibility - (Direct and Indirect) Hemolysis - ASTM
- *In Vitro* Hemocompatibility Assay - ISO
- Complement Activation (Direct) Assay - ISO
- *In Vivo* Thrombogenicity Assay - ISO, and
- Unactivated Partial Thromboplastin Time - ISO

All test results demonstrated the materials, manufacturing processes, and design of the BigBoss™ Catheters met the established performance criteria and will perform as intended.

Summary:
Based upon the intended use and descriptive information provided in this pre-market notification, the BridgePoint Medical BigBoss™ Catheters have been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN - 4 2012

BridgePoint Medical, Inc.
c/o Jill Munsinger
13355 10th Ave N, #110
Plymouth, MN 55441

Re: K113589
Trade/Device Name: BigBoss™ Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 01, 2011
Received: December 05, 2011

Dear Ms. Munsinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

8. INDICATIONS FOR USE STATEMENT

510(k) Number: (TBA)

Device Name: **BridgePoint Medical BigBoss™ Catheter**

Indications For Use:

The BridgePoint Medical BigBoss™ Catheter is intended to be used in conjunction with a guidewire in order to access discrete regions of the peripheral vasculature. It may be used to facilitate placement of guidewires and other interventional devices.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113589